



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 09/835,992 | 04/17/2001 | Yuichi Obata | L0461/7112 (JRV/MXA) | 6680 |
| 23628 | 7590 | 06/02/2004 | EXAMINER | |
| WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211 | | | BLANCHARD, DAVID J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/835,992 | OBATA, YUICHI | |
| | Examiner | Art Unit | |
| | David J Blanchard | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 March 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 13-15,31-32 and 62 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 13-15, 31-32 and 62 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. It appears that claims that claim 62 has been misnumbered because claims 33-61 apparently have not been previously presented in this Application. Therefore, to maintain the consecutive numbering of the claims in accordance with 37 C.F.R 1.126, claim 62 has been renumbered as claim 33.
2. Claims 13-15 and 31-33 are pending.

Claim 31 has been amended.

Claim 33 has been added.
3. Claims 13-15 and 31-33 are under examination.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Applicant's acknowledged the interview summary mailed on 3/8/2004 and indicated that there was no outstanding enablement rejection of the claims and no such rejection was discussed during the telephonic interview of 3/5/2004. Applicant is correct in that the enablement rejection was not discussed during the telephonic interview of 3/5/2004. However, claims 13-15, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, enablement. Applicant is directed to item #8 under the separate heading **Response to Arguments** of the Office Action mailed 12/11/2003. In view of this, the arguments presented under the heading "Rejections Under 35 U.S.C. 112, First Paragraph" (pages 5-7 of the response) in the response filed 3/15/2004 will be treated as being directed to the written description rejection and not the enablement rejection.

Claim Objections

6. Claim 31 is objected to because of the following informalities:

The word "regimen" appears to be misspelled as "regime" in claim 31, first and last lines.

Appropriate correction is required.

Objections/Rejections Withdrawn

7. The objections to the disclosure as not containing the patent numbers for USSNs 08/896,164; 08/850,980; and 08/479,328 is withdrawn in view of the amendments to the disclosure to include the corresponding patent numbers.

8. The objections to claim 31 for being drawn to non-elected inventions as well as other informalities is withdrawn in view of the amendments to the claim.

9. The rejection of claims 31-32, parts a and b, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention is withdrawn in view of the amendments to the claims.

Response to Arguments/New Grounds of rejections

10. The rejection of claims 31-32, part c, and applied to newly added claim 33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention is MAINTAINED.

The response filed 3/15/2004 has been carefully considered, but is deemed not to be persuasive. The response states that the progress of a therapeutic regime can be followed in which the presence or level of antibodies to SCP-X/SCP-2 is determined at separate times. In response to this argument there is still no indication as to whether the level of antibodies to SCP-X/SCP-2 will increase or decrease over the course of a therapeutic regimen designed to alleviate gastric cancer.

11. The rejection of claims 13-15, 31 and 32 and applied to newly added claim 33 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is MAINTAINED.

The response filed 3/15/2004 has been carefully considered but is deemed not to be persuasive because the response did not address the rejection.

12. The rejection of claims 13-15, 31 and 32 and applied to newly added claim 33 under 35 U.S.C. 112, first paragraph, written description, as containing subject matter, which was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed had possession of the claimed invention is MAINTAINED.

The response filed 3/15/2004 has been carefully considered, but is deemed not to be persuasive. The response summarizes the telephonic interview of 3/5/2004. The response states that the patients in the study submitted in the Declaration (dated 6/24/2003, submitted 7/11/2004) were not selected, and the results in the Declaration

demonstrate the diagnostic value of the claimed method. It was added that normal non-cancerous patients had no sterol carrier protein-X/sterol carrier protein-2 antibodies and the technique would therefore, identify only those patients with gastric cancer. The response also states that the sequences found using the SEREX method had to have open reading frames, which were the same as the sterol carrier protein-X protein in gastric cancer in order to be identified using this method and Applicant has supplied the open reading frames for SEQ ID NOS:19-22 (Exhibits A-1 through A-4). In response to this argument the nucleic acids of SEQ ID NOS:19-22 do not encode the sterol carrier protein-X/sterol carrier protein-2 as evidenced by Exhibits A-1 through A-4. Genbank Accession No. I38205 (see attached to back of this Office Action) teaches that the sterol carrier protein-X/sterol carrier protein-2 is 547 amino acids in length and none of SEQ ID NOS:19-22 encode this protein. Exhibits A-1 through A-4 show that the nucleic acids of SEQ ID NOS:19-22 only encode short polypeptide fragments and there is no indication how the structure of these polypeptide fragments are related to the structure of the sterol carrier protein-X/sterol carrier protein-2 as taught in the prior art. It is noted that Frame 3 (5'3') of SEQ ID NO:21 appears to encode a fragment of the sterol carrier protein-X/sterol carrier protein-2 corresponding to amino acids 156-378 of Genbank Accession No. I38205, but again there is no structure/function correlation between the fragment of SEQ ID NO:21 and the sterol carrier protein-X/sterol carrier protein-2. Thus, it is unclear if antibodies produced in vivo against a conformational dependent epitope of the sterol carrier protein-X/sterol carrier protein-2 protein in gastric cancer patients would even react with the sequential epitope of the fragment of SEQ ID NO:21.

The response further states that the identified sequences matched nucleic acid molecules encoding the sterol carrier protein-X. Again, as indicated above SEQ ID NOS:19-22 do not encode the sterol carrier protein-X/sterol carrier protein-2 as there are numerous stop codons throughout the reading frames of SEQ ID NOS:19-22 (see Exhibits A-1 through A-4). With respect to the function of the sterol carrier protein-X or how to identify which region the nucleic acid sequence matched, the response by Dr. Skipper states that it is only required that the nucleic acid encode an immunogenic protein and from knowing the nucleic acid sequence it would be routine to determine the corresponding region of sterol carrier protein-X. Again, the evidence provided in Exhibits A-1 through A-4 does not clearly identify what the polypeptide fragments encoded by SEQ ID NOS:19-22 actually are or what the structure/function relationship is between SEQ ID NOS:19-22 and the sterol carrier protein-X/sterol carrier protein-2.

Conclusions

13. No claim is allowed.
14. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER